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# (54) OCCLUSION OF BODY CHANNELS

(71) We, MEDLINE AB, a Swedish company, of Wallingatan 37, S-111 24 Stockholm, Sweden, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to a device for temporary or permanent occlusion of channels or hollow spaces in human or animal bodies, particularly oviducts and spermatic ducts.

Human and animal bodies contain a vast number of channels, through which fluid and/or other substances or objects can pass or be transported. In certain cases, it is desirable to disrupt such a passage. For contraceptice purposes the spermatic ducts and the oviducts (fallopian tubes) could thus be occluded, whereby the passage of ova and sperms is prevented. In certain vascular diseases, for instance, it may be desired to stop the flow of blood through certain blood vessels. This is possible both on the arterial and vein side of the circulation. The methods hitherto used for this purpose have had disadvantages such as, for instance, that the passage through the channel has been difficult to occlude completely and/or to reopen, when desired. The means used for this purpose have brought problems of fitting; in the case of contraceptive devices such as described in the British Patent Specification No. 1 460 077 there have been problems in providing an occlusion of the correct size.

It has now be found that these disadvantages can be eliminated by using a body consisting of a hydrogel, which, when brought into contact with a body fluid, swells at least 20%. Apart from this swelling, the body is to be essentially inert to the body fluids and to other surrounding tissues. This swelling of the body in contact with body fluid is preferably at least 40%, e.g. at least 80%. It could be varied between 20 and 300%. The channels in human being and animals, which can be occluded by this device are, for example, blood vessels, urethers, spermatic ducts and oviducts.

The geometric form of the body is not critical and it can be essentially cylindrical, spherical or egg-shaped. However, it has preferably a circular cross-section in the section corresponding to that of the channel to be occluded. This cross-section of the body is preferably so much smaller than the cross-section of the channel that the body can conveniently be introduced along the channel.

The device according to the invention is particularly suited for use as a contraceptive device. In this use the body is interted into the spermatic ducts or the oviducts. The body is in this case preferably attached to a thread in such a way that it can be withdrawn, normally without a surgical incision. This thread can be made of an X-ray opaque material enabling localization of the position of the body.

The body itself can also possibly contain substances providing X-ray contrast.

When in contact with the body fluid the material of the body swells at least 20%, preferably at least 40%, e.g. at least 80%, and may even swell as much as 300%. In other respects, the material should be essentially inert and harmless to the body fluid and surrounding tissues and should not be absorbed by the human body. Suitable hydrogels for this purpose are polymers and copolymers of acrylic type, as e.g. cross-linked polyacrylamide and polymers and copolymers of methacrylic esters having at least one hydroxy radical in the side chain. A preferred monomer is 2-hydroxy-ethyl-methacrylate wherein the ester moiety can, for instance, derive from ethylene glycol or triethylene glycol. 2,3 - dihydroxypropyl methacrylate is also useful, for instance.

The body should be essentially elastic and plastic only to a very small extent. In unswollen (non-hydrated) state it may be stiff and/or hard (rigid), but should preferably soften in swelling. The body can con-

tain reinforcing material, e.g. armouring material, and also material making it more X-ray opaque, e.g. salts of barium or bismuth.

In use, the body is introduced into a channel in the unswollen state and will thereafter swell, when in contact with the body fluid, so that the body, which can pass through the channel when inserted, will swell and effectively contact the walls of the channel. Through the pressure then exerted by the walls on the body the elastic body will be slightly compressed simultaneously with a possible expansion of the elastic walls of the channel. In this way the body will fill the whole cross-section of the channel and prevent anything from passing through the channel simultaneously with the body being anchored in position. After insertion into an oviduct, the passage of ova to the uterus and spermatozoa, respectively, upwards through the oviduct to the unfertilized ovum will be prevented. After occlusion of a spermatic duct the outward passage of the spermatozoa will be prevented and a good contraceptive action is achieved. If desired, the inserted bodies can be withdrawn by operation or, as is the case when inserted in an oviduct, by extraction through the uterus in the case where the body is provided with an attached thread by which said extraction can be performed.

WHAT WE CLAIM IS:—

1. A device for at least temporarily occluding channels or hollow spaces in human beings and animals, said device comprising a body adapted to be inserted into said channel or hollow space and made of a hydrogel which swells at least 20% when in contact with body fluid, and which is otherwise essentially inert to body fluid and surrounding tissues.

2. A device according to claim 1, wherein the material swells at least 40% and preferably at least 80% when in contact with body fluid.

3. A device according to claim 1 or claim 2, wherein the hydrogel is of acrylic type.

4. A device according to claim 3, wherein said hydrogel is a polymer or copolymer of methacrylic esters having at least one hydroxy radical in the side chain.

5. A device according to claim 4, wherein the ester moiety of the methacrylic ester is derived from a polyhydric alcohol.

6. A device according to any one of claims 1 to 5, wherein said body contains an X-ray opaque material.

7. A device according to any one of claims 1 to 6, wherein an indicator thread is built in or attached to the body, said indicator thread being optionally X-ray opaque.

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